FDA 510(k) Premarket Notification

K183457 Zimmer Biomet 12/14 CoCr Femoral Head and Freedom Head

CLEARED

Nov 5, 2019
327 days to decision

K183457 · Product code: **LPH** · Orthopedic
Source: https://www.510kdatabase.net/k183457/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Metal/polymer, Porous Uncemented (LPH)
Date received	Dec 13, 2018
Decision date	Nov 5, 2019
Days to decision	327 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Zimmer, Inc.**
Location	Warsaw, IN, US
Contact	Rebecca Nofiz
Website	https://www.zimmerbiomet.com
510(k) history	373 submissions · 352 cleared · 1976-2026

Zimmer, Inc. is a leading orthopedic medical device manufacturer based in Warsaw, US. The company specializes in innovative surgical implants and trauma solutions. Zimmer, Inc. maintains a strong FDA 510(k) regulatory record with cleared devices from total submissions since 1976. Orthopedic devices represent approximately 90% of the company's submission portfolio. The company remains actively engaged in product development, with the latest FDA 510(k) clearance in 2026. Recent cleared devices reflect the company's focus on joint reconstruction and trauma fixation. Notable ...

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k183457/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 16, 2026